

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE,

Plaintiffs,

v.

AMGEN, INC.

Defendant.

GENENTECH, INC. and CITY OF HOPE,

Plaintiffs,

v.

AMGEN, INC.

Defendant.

Civ. No. 17-1407- CFC, Consol.

Civ. No. 18-924-CFC

REPORT AND RECOMMENDATION OF SPECIAL MASTER

Rodney A. Smolla, Special Master

District Court Judge Colm Connolly assigned these consolidated matters to the Special Master in a Memorandum Order entered on March 30, 2020. The District Court's order broadly instructed the Special Master to determine whether the sealed

redacted filings of the parties comply with the legal principles that govern the sealing of documents filed in federal judicial proceedings as established by the Supreme Court of the United States, the United States Court of Appeals for the Third Circuit, and the Federal Rules of Civil Procedure.

This Report and Recommendation: (1) describes the process through which the duties of the Special Master were completed; (2) briefly summarizes the applicable legal principles governing sealing; (3) recites the legal positions on the issues taken by the parties and explains the Special Master's approval and endorsement of their positions; and (4) concludes with a recommended order detailing the mechanics of how the parties should comply with this Report and Recommendation, to ensure that all material that should be unsealed is unsealed, and all that should remain sealed remains sealed.¹

A separate Sealed Appendix is filed contemporaneously with this Report and Recommendation. That Sealed Appendix contains a document-by-document review, in which the nature of every retained sealing or partial redaction is described, and the legal basis justifying continued sealing or redaction is succinctly explained.

¹ The recitation of law in this Report and Recommendation has been kept short. The Court is well-familiar with the controlling principles. The parties, through the initial guidance provided by the Special Master, and as evidenced in their thorough subsequent briefing, are as well. There is no disagreement as to the guiding legal principles.

I. The Process

The Parties and the Special Master agreed on a process for streamlining the review ordered by Judge Connolly and mandated by Third Circuit precedent. It may well serve as a useful model for future similar undertakings. The Special Master issued an Interim Order providing legal guidance to the parties regarding the nature of material that should not be sealed, and the nature of material that could justifiably be sealed, and the nature of the factual showing required to justify sealing. The Parties then engaged in their own self-review of all previously sealed material, engaging in a self-critique in which material previously filed under seal was voluntarily designated for unsealing. As to filings that, in whole or in part, should in either Party's view remain sealed, the Parties submitted to the Special Master the proffered legal and factual justifications. This process undoubtedly saved a great deal of time and expense. Even so, between them the Parties still submitted several hundred principal documents or attached exhibits for which continued sealing was urged, in whole or in part. As to those documents, the Special Master considered the Parties' legal submissions and the Parties' application of law to fact as to each document. As required by Third Circuit precedent, each specific sealing and redaction was reviewed by the Special Master.

II. The Applicable Legal Principles

A. The Three Tiers of Review

Three discrete bodies of law govern the principles pertaining to confidentiality, sealing, and redactions of documents in federal court litigation. They apply in ascending orders of scrutiny.

First, there are principles governing the issuance of protective orders in federal litigation. These principles emanate from Rule 26(c) of the Federal Rules of Civil Procedure, and the attendant gloss courts have applied to the application of Rule 26(c). *See Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 783-92 (3d Cir. 1994).

Second, federal courts recognize a common-law right of access to judicial records. “The existence of a common law right of access to judicial proceedings and to inspect judicial records is beyond dispute.” *Publicker Industries, Inc. v. Cohen*, 733 F.2d 1059, 1066 (3d Cir. 1984). There is a “presumption in favor of access to ‘public records and documents, including judicial records and documents.’” *Bank of America National Trust & Savings Association v. Hotel Rittenhouse Associates*, 800 F.2d at 343, *quoting Nixon v. Warner Communications, Inc.*, 435 U.S. 589, 597 (1978).

Third, “the public and the press have a First Amendment right of access to civil trials.” *In re Avandia Marketing Sales Practices & Product Liability Litigation*, 924 F.3d 662, 673 (3d Cir. 2019), *citing Publicker*, 733 F.2d at 1070. “[T]he First

Amendment, independent of the common law, protects the public’s right of access to the records of civil proceedings.” *Republic of Philippines v. Westinghouse Electric Corporation*, 949 F.2d 653, 659 (3d Cir. 1991), citing *Publicker*, 733 F.2d at 1070. “The First Amendment right of access requires a much higher showing than the common law right to access before a judicial proceeding can be sealed.” *In re Cendant Corp.*, 260 F.3d 183, 198 n. 13 (3d Cir. 2001). Any restriction on the First Amendment right of public access is “evaluated under strict scrutiny.” *Avandia*, 924 F.3d at 673, quoting *PG Publishing Company v. Aichele*, 705 F.3d 91, 104 (3d Cir. 2013).

Of these three, it is the middle tier, the common-law access right, that is principally in play in this Report and Recommendation.

B. The Common-Law Right of Access

1. The *Avandia* Guidance

While not purporting to articulate exhaustively what substantive showings will justify sealing or redacting a judicial record and what showings will not, the Third Circuit’s landmark ruling in *Avandia* did provide substantial guidance. *Avandia* confirmed the long-standing truism that the presumption of public access is “not absolute.” *Avandia*, 924 F.3d at 672, quoting *Bank of America*, 800 F.2d at 344. The presumption of public access *may* be overcome.

The critical divide is the distinction between material containing palpable trade secrets or proprietary business practices that will produce present commercial and competitive harm, on the one hand, and vague, conclusory assertions of commercial or competitive harm, or assertions that in fact appear grounded in reputational interests and embarrassment, on the other. A party's “‘vague assertions that the transcript contains secretive business information, and that disclosure would render [it] at a tactical disadvantage’ [are] insufficient to overcome that strong presumption.” *Avandia*, 924 F.3d at 676, *quoting LEAP Sys., Inc. v. MoneyTrax, Inc.*, 638 F.3d 216, 221-22 (3d Cir. 2011). The touchstone is the persuasive demonstration of specific, concrete, particularized of harm.

2. The *Publicker* Categories

The Third Circuit's 1984 opinion in *Publicker*, decided some 25 years prior to *Avandia*, endures as one of the most important substantive guides to what material may justifiably remain sealed. In a paragraph describing situations in which sealing could be justified, the Third Circuit postulated three categories: one involving “the content of the information at issue,” a second “the relationship of the parties,” and the third “the nature of the controversy.” *Publicker*, at 733 F.2d at 1073.

The Third Circuit then offered examples. For “the content of the information,” it used as an example “safeguarding a trade secret.” *Id.* For the “relationship of the parties,” it posited a suit by a client to prevent a lawyer from

disclosing confidential information protected by the attorney-client privilege. *Id.* The Third Circuit then gave as an example of “the nature of the controversy,” a passage which reads in its entirety: “A similar situation would be presented where there is a binding contractual obligation not to disclose certain information which to the court seems innocuous but newsworthy; in that situation unbridled disclosure of the nature of the controversy would deprive the litigant of his right to enforce a legal obligation.” *Id.* at 1073-74.

3. The Carve-Out for Discovery Motions

In *Leucadia, Inc. v. Applied Extrusion Technologies, Inc.*, 998 F.2d 157 (3d Cir. 1993), the Third Circuit held that the common-law right of access did *not* attach to discovery motions. In excluding “discovery motions,” *Leucadia* relied heavily on the fundamental principle that underlying discovery material *itself* is not a judicial record. There is no common law right of access to “raw discovery.” *Id.* at 157. If in the course of discovery, disputes arise, parties may file “discovery motions” seeking the intervention of a court to resolve the disputes. Those motions may require attachment of “raw discovery” materials, such as excerpts from depositions or interrogatory answers. The core learning of *Leucadia* is that the common-law right of access does not attach to such motions, or their exhibits containing raw discovery, because this would have the effect of converting material that is normally not a “judicial record” into material that is. The key passage in *Leucadia* thus

explained that “a holding that discovery motions and supporting materials are subject to a presumptive right of access would make raw discovery, ordinarily inaccessible to the public, accessible merely because it had to be included in motions precipitated by inadequate discovery responses or overly aggressive discovery demands.” *Id.* at 157.

4. The Procedural Requirements

Avandia contemplates a rigorous process of judicial review. The right of access must not be demoted to “a mere formality.” *Avandia*, 924 F.3d at 676. To ensure that proper weight is given to “the public’s strong interest in the openness of judicial records,” a District Court must engage in “a document-by-document review.” *Id.* Casual, superficial review does not suffice. “Again, the strong presumption of openness inherent in the common law right of access ‘disallows the routine and perfunctory closing of judicial records.’” *Id.*, citing *In re Cendant Corp.*, 260 F.3d at 193-94.

The substantive and procedural standards that must be met to overcome the presumption of access are onerous by definition and design. The party seeking to seal judicial records must satisfy “a heavy burden.” *Miller v. Indiana Hospital*, 16 F.3d 549, 551 (3d Cir. 1994). The party seeking to have a record sealed “must show that ‘the material is the kind of information that courts will protect and that disclosure will work a clearly defined and serious injury to the party seeking

closure.” *Avandia*, 924 F.3d at 677-78, *quoting Miller*, 16 F.3d at 55. In granting a sealing order, a “District Court should articulate ‘the compelling[,] countervailing interests to be protected,’ make ‘specific findings on the record concerning the effects of disclosure, and provide[] an opportunity for interested third parties to be heard.’” *Avandia*, 924 F.3d at 677-78, *quoting In re Cendant Corp.*, 260 F.3d at 194. “‘In delineating the injury to be prevented, specificity is essential.’” *Id.* Generalized incantations that secrecy is required to prevent competitive or commercial harm are not enough to carry the movant’s burden. “‘Broad allegations of harm, bereft of specific examples or articulated reasoning, are insufficient.’” *Id.*

The factfinding required by district courts must be careful and meticulous in order to vindicate the rights of the public and the integrity of the judicial process itself, notwithstanding the private interests or preferences of the litigants, even when they are in agreement. “[C]areful factfinding and balancing of competing interests is required before the strong presumption of openness can be overcome by the secrecy interests of private litigants.” *Avandia*, 924 F.3d at 677-78, *quoting Leucadia*, 998 F.2d at 167.

The Third Circuit’s *Avandia* opinion mandates a “document-by-document” review of the claimed propriety of sealing. “[I]t must be clear from the record that the district court engaged in a particularized, deliberate assessment of the standard as it applies to each disputed document.” *Id.*

III. The Submissions of the Parties

A. Genentech's Legal Arguments

Genentech grounds its claims for continued sealing or redaction of certain designated materials on its need to retain the confidentiality of proprietary trade secrets or other competitively sensitive information. Such material is at the core of that type of material that is routinely treated as overcoming the common-law presumption of access. The revelation of trade secrets, or of other competitively sensitive information that may not meet the formal definition of “trade secret,” but nonetheless is shown to be of the nature that would work palpable competitive harm on a party, is precisely the type of material most likely to successfully rebut the presumption favoring access. As the Supreme Court observed in *Nixon v. Warner Communications*, “courts have refused to permit their files to serve as ... sources of business information that might harm a litigant’s competitive standing.” *Nixon*, 435 U.S. at 598. So too, the Third Circuit has recognized that “[d]ocuments containing trade secrets or other confidential business information may be protected from disclosure.” *Leucadia*, 998 F.2d at 166. Thus “[d]espite the presumption, courts may deny access to judicial records, for example, where they are sources of business information that might harm a litigant’s competitive standing.” *Littlejohn v. Bic Corp.*, 851 F.2d 673, 678 (3d Cir. 1988), *citing Nixon*, 435 U.S. at 598.

B. Amgen's Legal Arguments

Amgen groups its proffered retained sealings and redactions into four categories:

- (1) Sensitive and proprietary manufacturing and trade secret information;
- (2) Sensitive and confidential material reflecting commercial and regulatory intelligence, planning and/or strategy;
- (3) Sensitive and proprietary legal information, including privileged material produced in response to the Court's waiver orders; and
- (4) Sensitive and confidential pre-litigation material reflecting the parties' substantive exchanges during the non-public pretrial exchanges under the Biologics Price Competition and Innovation Act ("BPCIA"), 42 U.S.C. § 262.

Sealing of material is legally justified under all four of these categories.

The first two categories identified by Amgen are essentially alternative phrasings to the same principles relied upon by Genentech. They fall well within the confines of the types of material that the Third Circuit has identified as appropriate for sealing under the standards of *Publiker*, *Avandia*, and related cases.

As to the third category, confidential legal information is the sort of relationship-based exception to the common-law access rule specifically described in *Publiker*.

And the final category, confidential exchanges arising from the BPCIA

process, is an extraneously imposed confidentiality obligation—imposed by Congress, after all—carrying even greater weight than *Publicker*’s recognition that contractual obligations may justify sealing or redaction. The BPCIA is a process prescribed by Congress to streamline biosimilar product litigation through negotiations directed at identifying patents to litigate or license. The Act by its terms treats these exchanges as confidential. 42 U.S.C. § 262(l)(1)(C) (“No person that receives confidential information . . . shall disclose any confidential information to any other person or entity, including the reference product sponsor, without the prior written consent of the [biosimilar] applicant.”).

On top of these four substantive justifications, much of the material designated for continued sealing or redaction by both parties falls squarely within the carve-out for discovery motions and accompanying attachments recognized in *Leucadia*.

C. Factual Documentation

Both Genentech and Amgen provided comprehensive and persuasive factual explanation and documentation as to why the material each identified as appropriate for sealing does in fact meet the criteria summarized above. Both parties submitted numerous, lengthy, and detailed factual declarations by highly placed and expert employees within their respective companies. Those substantial declarations explained generally, and with reference to specific documents in the record, the

factual predicate for continued sealing. The positions and qualifications of those declarants, as well as the substance of their presentations, are discussed as germane in the Sealed Appendix.

In generic terms, without broaching reference to specific redacted or sealed material, the submissions of the parties were in alignment in describing the intensely competitive scientific and business arena in which they compete. Both have persuasively established the justification for sealing various docket entries and accompanying exhibits. The proffered justifications include, among others, trade secrets, proprietary scientific research, highly sensitive manufacturing information, the confidential terms of settlement and license agreements, business intelligence, regulatory strategies, and confidential legal information.

The parties have documented how the information contained in their proposed sealings and redactions, if disclosed, would visit upon them present commercial and competitive harm. In revealing sensitive and confidential business information to their competitors, they would be supplying those competitors with information regarding their knowledge, operations, capabilities, and strategies.

In some instances, the prospect of harm is linear and direct. Competitors in the highly-competitive biologics marketplace could use Amgen's or Genentech's own research to the competitors' competitive advantage to more effectively develop and manufacture products.

In other instances, the harm is less linear and direct, but still entirely real. Both parties, as many in the industry, are constantly involved in litigation. Revelation of the terms of settlement agreements, which are among the documents for which continued sealing is often sought, could place the parties at a demonstrable disadvantage in navigating and negotiating other litigation contests with competitors in the same pharmaceutical space.

The parties have established that in the highly competitive pharmaceutical industry environment, even seemingly minor pieces of information about a pharmaceutical company can be valuable to its competitors. So too, both parties have demonstrated that they go to extraordinary lengths to safeguard the integrity of their confidential information, both through the firewalls they impose to protect the information from outsiders, and the closely guarded “need to know” protocols they impose internally on their own employees.

One size does not fit all in describing the specific nature of the proposed redactions. In some instances the material reflects commercial intelligence—research and strategic analysis of factors such as anticipated market share and penetration, sales volume, or pricing and discount strategy. These competitive assessments include inward-facing judgments on the parties’ own capacities as well as outward-facing judgments on the capacities of others. The proffered redactions also include information on the approaches of the parties to interfacing with

government regulators in their highly regulated industry. The parties each expend substantial resources in conceptualizing how best to secure regulatory approval of their products. Public revelation of those strategies could undercut the effectiveness of those efforts, or provide competitors with value information they could exploit to their own advantage.

In sum, the parties have engaged in appropriate self-restraint and self-scrutiny in placing into the public domain much of the material previously filed under seal. Having carefully scrutinized the sealings and redactions they seek to maintain, the Special Master approves and recommends continued sealing and redaction, as detailed more specifically in the accompanying Sealed Appendix.

IV. Recommended Order

This litigation has been expansive, and the mechanics of executing the operational directives of this Report and Recommendation are fraught with the potential for inadvertent error. The guiding principles are simple enough:

(1) Any document previously sealed that is now to be unsealed in its entirety should be unsealed.

(2) Any document previously sealed in its entirety that is now to continue to be sealed in its entirety should remain sealed.

(3) Any document previously sealed in its entirety, or redacted in part, which is now to retain some justifiable redactions, but narrowed from the prior entire

sealing or redacted sealing, should be re-filed in its new form, with only the approved narrowed redactions continued.

To implement these principles, the Parties have already conferred with the Clerk of the Court. As a result of that consultation, this Report and Recommendation recommends to the Court that the Parties be ordered to meet and confer and file a joint submission to the Clerk of Court, in the form of an Appendix (as opposed to document-by-document re-filings), with a courtesy copy to the Special Master, that will: (1) identify those filings that were previously sealed in whole or in part that should now be entirely unsealed; (2) identify those documents previously sealed that are now to be continued to be sealed in their entirety; and (3) compile in the one Appendix filing new versions of all documents previously filed entirely under seal or with redactions, in their new form, with the redactions narrowed as approved by the Special Master as listed in the Sealed Appendix, with the appropriate previously sealed or redacted material now public, and the continued and approved material redacted.